



MEDICAL GASES

CRYOGENIC-GASES TERMINAL AUTOMATION SYSTEM

DESCRIPTION

Medical gases are an important part of the gas industry and subject to strict requirements in production, monitoring and sales. CRYO.TAS includes all the necessary prerequisites for storage, batch formation, transport and traceability of the medical products. All requirements from the underlying regulations and authority specifications are met.

Thus, CRYO.TAS includes all functions and prerequisites from the EG-GMP guideline parts I and II.

The measures for compliance with the specifications are not only part of the system software, but also include all system parts.

Additionally, the system can be expanded by the function of electronic release (add-on module). This module was developed in cooperation with the authorities to simplify the release processes of batches and effective substances, execute them independently of location and document them comprehensively.

sively.

The present scope of functions for the medical gases can also be used for other special products.

BENEFITS

- Seamless documentation of all processes
- Audit trail
- Automatic batch formation
- Generation of effective substance protocols
- Automatic notification of the release authorities
- Recording the OOS-results
- Add-on for release of medical batches independently of location
- Recording all results in release tabs
- Electronic 4-eye principle
- Maximum process safety

MEASURES AND SPECIAL FUNCTIONS FOR MEDICAL GASES

SYSTEM ADMINISTRATION

- Electronic 4-eye principle:
If there are any changes to medical products or any system components used for them, confirmation by another qualified person is required.
- Electronic release process (add-on):
Reporting batches to be released to the relevant persons via email (QP).
Remote review of the results and remote release with inspection of the release sequence.
Documentation of all release steps in the release tabs
- Own QP area in the system operation:
Definition of operating limitations for the specifications of medical products or changes to relevant system components.
- Approval Archive:
Archiving of all release steps with comments in the release archive.

LOADING POINTS

- Release of a loading point for loading of medical products only.

VEHICLES

- Definition of rights for loading medical products for transport containers.

DRIVER AND OPERATING STAFF

- Assessment type of medical products.
- Review for trainings performed and approvals for handling of medical products (e.g. hygiene training)

BATCH FORMATION

- Support of common batch formation for:
 - Real batch tank with finished medical product loading from batch tank
 - Continuous storage tank: Formation of an effective substance batch with effective substance loading. Then formation of the finished medical product in the transport container.

LOCKING MED. PRODUCTS

- Automatic lock at:
 - Unauthorized opening of valves at the batch tank.
 - Non-performance of the specification at cyclic tank test (only continuous storage tank).
 - Change to a product specification of a medical product.
 - Change of a function parameter that is marked as "quality relevant" for medical products.
 - Defective or incorrect test equipment for monitoring medical products.

GENERAL SYSTEM FUNCTIONS

- Transport container identification by RFID transponder
- Person identification by RFID transponder
- 1:1 assignment of loading point and analysis point. This precludes swapping of transport tanks.

VALIDATION CAPACITY

- System development and expansions are generally performed according to the V model purs. to GMP.
- EG-GMP parts I and II; EC-GMP Appendix 6 compliant
- Service and support contracts contain the service of "Change management" for your entire system installation.
- Compliance with all directives and specifications for a possible system validation

OPERATING INTERFACE QP-AREA

The screenshot shows the 'QP Products' interface in the CRYO.TAS Master System. The main table lists products with columns for List name, Product number, Product group, Pre-analysis, Post-analysis, Mixed product, Error consideration, Modified date, and Editor. Below this, the 'Product release' tab is active, showing a table of release steps with columns for Step no., Person, and Modified date.

#	List name	Product num	Product group	Pre-analysis	Post-analysis	Mixed product	Error consideration	Modified	Editor
	LOXmec	16002.5 10f	LOX	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	01/04/2014	Hett
	Test LO:	16002.5 Fer	LOX	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21/01/2014	Ollig
	LOXMED	16002.5 me	LOX	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	19/07/2013	Hett
	LOX 2.5	16002.5 PX	LOX	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	15/07/2013	Hett
	Sauerarb:	16002.5 Wf	LOX	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	15/07/2013	Hett
	Tankapt	16002.5 Wf	LOX	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	03/06/2013	Hett
	Test Sat	16002.5 Wf	LOX	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	05/06/2013	Hett
	LOX 3.5	16003.5 PX	LOX	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	30/09/2013	Hett
	Stickstol	17002.5 Ph:	LIN	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	19/03/2014	Hett
	Stickstol	17002.5 Ph:	LIN	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	19/03/2014	Hett

Step no.	Person	Modified	Editor
1	Bau	17/07/2015	Bauer, Wolfgang
2	Düb	17/07/2015	Bauer, Wolfgang
3	Beh	17/07/2015	Bauer, Wolfgang

FIG.: QP-PRODUCTS

Definition of the release steps for the electronic release in the QP area for the administration of the medical products.

Any number of release steps can be defined for a medical product. The order of the re-

leases is defined with the step number. After formation of a batch of a product with release steps, the persons entered in the product release are automatically informed about the required release process. The releases can only be performed in the specified order. Every person must authenticate individually for the release process.

The screenshot shows the 'Release container' interface. It displays a table of release containers with columns for Factory, Reserv. cod, Load date, Container i, License pla, Product, Product, Active, First custor, Batch number, Driver, Filling plac, only analy, OOS, Attachment, Modified, and Editor. Below this, the 'Release container' tab is active, showing a table of release steps with columns for Step no., Person for approval, Procedure No., is approved, is acknowledged, Modified, and Editor. At the bottom, there is a section for 'Batch number' and 'Step number' with a table of analysis results.

Time stamp	Procedure No.	Chem. symb.	Operator	Analysis limit	Value	%	Unit
09.04.2014 06:54	40919-20140409-002_M	O2	>=	99.50000	99.96		%
09.04.2014 06:54	40919-20140409-002_M	CO	<=	5.00000	0.10		ppm
09.04.2014 06:54	40919-20140409-002_M	CO2	<=	10.00000	0.11		ppm

Step no.	Person for approval	Procedure No.	is approved	is acknowledged	Modified	Editor
1	Ri	40919-20140409-002_M	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	09.04.2014 07:18	Ripl
2	Kr	40919-20140409-002_M	<input type="checkbox"/>	<input type="checkbox"/>	09.04.2014 07:15	
2	Ni	40919-20140409-002_M	<input type="checkbox"/>	<input type="checkbox"/>	09.04.2014 07:15	
3	Kr	40919-20140409-002_M	<input type="checkbox"/>	<input type="checkbox"/>	09.04.2014 07:15	
3	Ni	40919-20140409-002_M	<input type="checkbox"/>	<input type="checkbox"/>	09.04.2014 07:15	

FIG.: RELEASE VEHICLE

Example of a vehicle release after loading in the transport container. The release step no. 1, head of production, has already been performed.

After processing of the last release step, the system will automatically generate the effective substance limit log.

CRYO.TAS THE OVERALL CONCEPT

Tank-Management

- Product availability monitoring
- Lock and unlock of products
- Batch creation
- Special functions for medical- and food-products
- Calculation of loaded quantities

Analysis

- Automated gas path switching
- Test equipment- and calibration gas monitoring
- Auto-calibration
- Locking and unlocking of test equipment
- Connectivity to a wide range of sample point types (e.g. pipeline)

Entrance

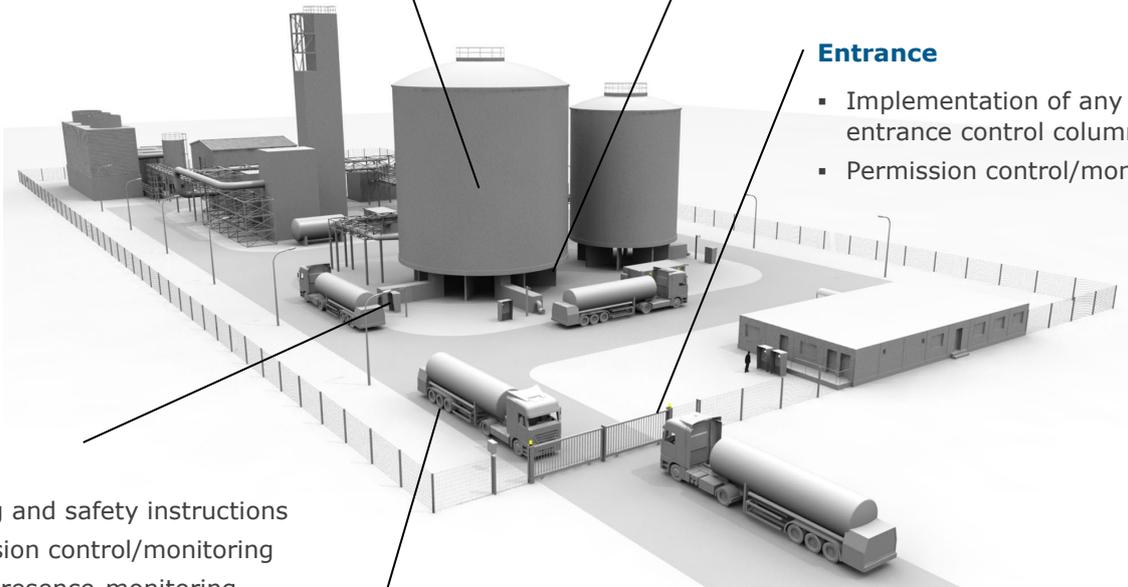
- Implementation of any number of entrance control columns
- Permission control/monitoring

Loading

- Loading and safety instructions
- Permission control/monitoring
- Force-presence-monitoring
- Quality assurance/analysis
- Blending functionality
- Off-loading
- Special functions for medical products
- Control of all field devices

SCALE.TAS

- Usage of any number of weigh bridges
- Free usage of entry- or exit weigh bridge, or both
- Creation of loading/transportation documents
- Quota control



INFORMATION

Would you like more information about the CRYO.TAS system? On the Internet you always get the latest information, or contact us directly. We are always ready to show you the performance of the system in a live presentation.

Simply contact:

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